

### **REMARKS**

According to the Office Action of December 17, 2007, the specification and pending claims 20-39 have been examined on their merits, and have been objected to and/or rejected under 35 U.S.C. §§ 112, 101, 102 and 103. In view of the amendments to the abstract and claims, and the below remarks, Applicants respectfully request reconsideration and withdrawal of the objections and rejections.

#### **Objection to the Abstract**

The abstract was objected to because it exceeded 150 words. Applicants have amended the abstract. A clean copy of the amended abstract is attached hereto. The amended abstract contains fewer than 150 words. Accordingly, withdrawal of this objection is respectfully requested.

#### **Objection to the Claims**

The objection to claim 22 asserts that "said liquid" lacks antecedent basis. Claim 22 has been amended to recite "a liquid."

The objection of claim 23 asserts that "said pump means" lacks antecedent basis. Claim 23 has been amended to recite "a pump means."

The objection of claim 24 asserts that "said liquid containing means" lacks antecedent basis. Claim 24 has been amended to recite "a liquid containing means."

Accordingly, withdrawal of these objections is respectfully requested.

#### **Rejection under 35 U.S.C. § 112, Second Paragraph**

Claims 20-39 have been rejected under 35 U.S.C. § 112, second paragraph, as purportedly being indefinite. Specifically, the rejection is based on the recitation of "such as" in claims 20, 31 and 35. This recitation has been deleted. Accordingly, withdrawal of this rejection is respectfully requested.

**Rejection under 35 U.S.C. § 101**

Claims 20-34 have been rejected as purportedly failing to recite statutory subject matter. Applicants have adopted the Examiner's suggestion and amended the claims to recite "... a tubular means adapted to be introduced in said cavity ...." Accordingly, withdrawal of this rejection is respectfully requested.

**Rejections under 35 U.S.C. § 102**

Claims 35-37 have been rejected as purportedly being anticipated by Ayre (U.S. Pat. No. 3,540,432) or Lurie (U.S. Pat. No. 7,207,951). Applicants respectfully traverse these rejections for the reasons discussed below.

***I. Rejection based on Ayre***

The Office Action contends that claims 35 and 36 are anticipated by Ayre. On pages 3 and 4, the Office Action asserts that Ayre's glycerine acts as a flushing solution. However, Ayre's glycerine is not expelled from a sampler tube into a body cavity. Instead, it is placed on the head of the instrument prior to insertion into the cervix. In contrast, the recited flushing solution is expelled from the sampler tube into the body cavity. Since Ayre does not teach this limitation, it fails to teach each and every limitation recited in claims 35 and 36.

Additionally, as implied by the Office Action not rejecting claim 20 as anticipated by Ayre, Ayre does not teach the sampler tube recited in amended claims 35 and 36.

***II. Rejection based on Lurie***

The Office Action also contends that claims 35-37 are anticipated by Lurie. By not rejecting claim 20 as anticipated by Lurie, the Office Action acknowledges that Lurie does not teach the sampler tube recited in claim 20. Claims 35-37 have been amended to

recite the sampler tube of claim 20. Since Lurie fails to teach this limitation, it fails to teach each and every element recited in claims 35-37.

For these reasons, Applicants respectfully request that the rejections asserted under 35 U.S.C. § 102 be reconsidered and withdrawn.

### **Rejection under 35 U.S.C. § 103**

Claims 20-34 and 37-39 have been rejected under 35 U.S.C. § 103 as purportedly unpatentable over various combinations of Ayre, Suzuki (U.S. Pat. No. 4,781,699), Lurie, and/or Oster (U.S. Pat. No. 3,815,580). For the reasons discussed below, Applicants respectfully traverse these rejections.

#### **I. Rejection of claims 20-28 and 31**

On page 5, the Office Action contends that claims 20-28 and 31 are unpatentable over Ayre in view of Suzuki. However, the Office Action fails to establish that Ayre or Suzuki teach the recited central sampling opening.

According to MPEP § 2142, the Patent Office bears the burden of establishing a *prima facie* case of obviousness by providing reasons why the claimed invention would have been obvious in view of the combination of the references. In doing so, the Patent Office must consider all limitations recited in the claims. MPEP § 2143.03.

In this case, the Office Action fails to consider the central sampling opening limitations. Accordingly, it fails to establish a *prima facie* case of obviousness.

Additionally, the combination of the references does not teach multiple openings having a diameter of less than 5 mm. On page 5, the Office Action acknowledges that Ayre fails to disclose sample openings that are less than 5 mm in diameter (among other things) and claims that Suzuki overcomes this deficiency. However, Suzuki fails to teach a number of sampling openings having a diameter of less than 5 mm at a curved introduction end.

Suzuki is directed to a device for removing mucus from a uterocervical canal of an animal. The device comprises holes 3 for catching the mucus. The holes 3 are

positioned at about 10 to 15 cm from the tip of the catheter 2 (Suzuki at column 2, lines 58-63).

In pertinent part, claim 20 recites a “sampler ... comprising a tubular means adapted to be introduced in said cavity, the introduction end of which is curved to define a central sampling opening, ... said tubular means comprising ... only at the curved introduction end a number of sampling openings is provided having a diameter of less than 5 mm.”

“In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. [Citations omitted].” MPEP § 2141.02. In this case, the combination of Ayre and Suzuki does not teach a number of sampling opening only at the introduction end, and therefore it does not teach the recited invention as a whole. Ayre admittedly fails to teach the recited sample openings. Suzuki does not overcome this deficiency because Suzuki’s holes are positioned away from the tip, as opposed to at the introduction end.

The Office Action also fails to establish a motivation to combine Ayre and Suzuki. On page 6, the Office Action contends that “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ayre to include the use of small diameter openings as well as different type of a vacuum source, as per the teachings of Suzuki et al., since it would provide a device that has the ability to obtain mucus sample utilizing a vacuum source.”

To establish a *prima facie* case of obviousness, the Patent Office has the burden of identifying objective teachings in the prior art, or knowledge generally available to one of ordinary skill in the art, which would lead an individual to combine the relevant teachings of the references in the manner suggested by the Examiner. *In re Fritch*, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992); *In re Fine*, 5 U.S. P.Q.2d 1596, 1598 (Fed. Cir. 1988). “The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, 82 U.S.P.Q.2d

1385, 1396 (2007).” MPEP § 2143.01. Thus, some articulated reason with rational underpinning to support the legal conclusion of obviousness must be provided for the Examiner to meet his or her burden. MPEP § 2143.01, *citing KSR Int’l.*, 82 U.S.P.Q.2d at 1396 *quoting In re Kahn*, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed. Cir. 2006).

“[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR Int’l.*, 127 S.Ct. 1727, 1741. “[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does”. *Id.* Examples of rationales to support a *prima facie* showing of obviousness are provided in MPEP (Rev. Sept. 6, 2007) § 2143:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) “Obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teaching to arrive at the claimed invention.

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.

The reasoning behind this requirement is to ensure that hindsight is not used. MPEP § 2145. As set forth by MPEP § 2141, the Federal Circuit in "*In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that '[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.' Citation omitted."

In this case, there is no motivation stated in the Office Action to combine Ayre and Suzuki. The purported rationale provided on page 6 is only a conclusory statement based on an incorrect assumption that retrieving mucus samples using a vacuum source is desired in the art. This assumption is incorrect because Suzuki is not directed to retrieving mucus samples. Instead, it is directed to a device that removes mucus. It is apparent because the problem Suzuki's invention is directed to is the large quantity of mucus present in the cervical canal of a cow seven days after embryogeny (Suzuki at column 1, lines 21-22), and not collecting a cow's cervical mucus for study.

Moreover, these references cannot be combined because they are non-analogous to each other. According to MPEP § 2141.01,

[t]he examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. "Under the correct analysis, **any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed.** " *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1397 (2007).

(Emphasis added).

In this case, Ayre and Suzuki do not address similar needs or problems and are from different fields of endeavor. Suzuki is directed to removing mucus from cows after embryogeny. This is unrelated to Ayre's and the inventor's field of endeavor – sampling cells from the cervix. Therefore, Suzuki is a non-analogous reference, which cannot be relied upon to support a rejection under Section 103.

***II. Rejection of claims 29, 30 and 31***

Claims 29, 30 and 31 have been rejected as purportedly unpatentable over the combination of Ayre, Suzuki and Lurie. Applicants respectfully traverse this rejection for the reasons discussed above, and because Lurie does not overcome any of the above-identified deficiencies.

***III. Rejection of claims 33 and 34***

Claims 33 and 34 have been rejected as purportedly unpatentable over the combination of Ayre, Suzuki and Oster. Applicants respectfully traverse this rejection for the reasons discussed above, and because Oster does not overcome any of the above-identified deficiencies.

***IV. Rejection of claim 37***

Claim 37 has been rejected as purportedly unpatentable over the combination of Ayre and Lurie. As suggested by the tacit acknowledgement that claim 20 is not anticipated by Ayre or Lurie, Ayre and Lurie does not teach the sampler tube recited in claim 37 vis-à-vis the amendment to claims 35. Therefore, Applicants respectfully request that this rejection be reconsidered and withdrawn.

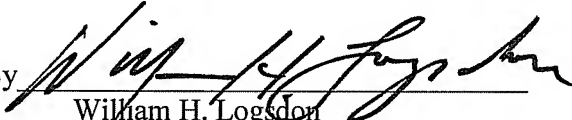
Application No. 10/528,417  
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Attorney Docket No. 0470-050863

**Conclusion**

In view of the amendments and remarks, Applicants respectfully request that all objections and rejections be reconsidered and withdrawn, and that all pending claims be allowed. Should the Examiner wish to discuss this matter further, the Examiner is encouraged to contact the Applicants' undersigned representative at (412) 471-8815.

Respectfully submitted,

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### **ABSTRACT**

-- Sampler for self-sampling of samples from a body cavity, such as cervical samples. Optimum accessibility of the cervix is achieved through the sampler comprising a rigid plastic tube which is rounded at the front side. During its introduction, the sampler can accurately be moved to the cervix. The sampler is surrounded by the vagina and can prevent leakage of flushing liquid, and it is possible to use a relatively small quantity of flushing liquid while producing a sample with a high concentration of cervical cells. It is possible to reach the sampling location in a simple and more accurate way which does not damage tissue. As a result of the tube simultaneously being designed as a cylinder for a plunger, it is possible, to flush the desired location with a solution using a cylinder-plunger and, to take the sample by drawing the plunger back. --